

Compliance Packaging Labeling

The Board requires in 18 VAC 110-20-340 that pharmacies that dispense compliance packaging do so in compliance with USP-NF standards. Compliance packaging that is comprised of a series of individual containers or pockets labeled with the specific date and time when the contents of that container are to be taken, and which may contain more than one different drug, must comply with USP-NF standards for customized patient medication packages. USP requires that if the packaging allows for the separation of the individual containers, that the labels for each individual container be labeled with the identity of each of the drug products contained within. However, the main packaging label must still contain all the requirements for any outpatient labeling in Virginia law including, but not limited to, patient name, drug name and strength, quantity, directions for use, prescriber's name, pharmacy or pharmacist name and address, date of initial dispensing, etc. In addition the main label must contain a physical description identifying each solid dosage form contained within the individual containers.

For residents of long term care or other inpatient facilities who are leaving the facility for short periods of time, the facility may want to send only those individual containers needed during the time the resident is away. If the needed containers are separated from the main package, then the containers sent with the resident will not contain all required labeling for an outpatient label.

The Board will consider this practice to be in compliance with labeling requirements provided the individual containers are labeled as described above, and provided the containers are sent packaged with other documentation that contains the complete information required for labeling. Such documentation could be a copy of the main compliance package label, a medication administration record containing all required information, or other document that contains all required information.